JUN 1 - 2005

K051133

510(K) SUMMARY
FOR THE
SIREMOBIL C 06

Submitted by:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

April 18, 2005

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Michael J. Andrews
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Phone: (610) 448-4599
Fax: (610) 448-1787

2. Device Name and Classification:

Trade Name:	ARCADIS Avantic
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	DXO

3. Substantial Equivalence:

The ARCADIS Avantic is substantially equivalent to the following devices:

Predicate Device Name	*510(k) Number*	*Clearance Date*	*Comparable Properties*
Siemens Siremobil C06 Trade name: ARCADIS Varic	K040066	02/12/2004	• Hardware • Control Software • Imaging system
Siemens AXIOM Artis U	K040675	06/10/2004	• X-ray features • Intended use

4. Device Description:

The ARCADIS Avantic is an x-ray system which consists of a mobile C-arm configured with a high frequency generator, X-ray tube assembly, image intensifier, TV camera, laser target devices, electronics cabinet, a monitor trolley and digital image storage system which consists of the digital memory device, image monitor(s), and user interface. The system is equipped with a footswitch and a hand switch for radiation release.

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5. Intended Use of the Device:

The ARCADIS Avantic is a mobile x-ray system which can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Digital Cine Mode DCM, Subtraction, and Roadmapping, which are necessary in performing a wide variety of clinical procedures. Clinical applications may include, but are not limited to card/vascular, gastroenterology, electrophysiology, urologic, orthopedic, neurologic, pediatrics, endoscopy, pain therapy and emergency room procedures

6. Summary of Technological Characteristics of the Devices Compared to the Predicate:

The ARCADIS Avantic is a modification to the ARCADIS Varic. Mechanically the changes are minor in design and style. The X-ray generator and X-ray tube are designed to provide the increased power.

The imaging chain reflects the current standard of 1024^2 image processing and display with flat screen monitors. An uninterruptable power supply provides additional safety to image and demographic data in the event of a power outage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Michael J. Andrews, Ph.D.
Senior Manager, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

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Re: K051133
Trade/Device Name: ARCADIS Avantic
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: April 29, 2005
Received: May 3, 2005

Dear Dr. Andrews:

This letter corrects our substantially equivalent letter of June 1, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051133
Device Name: ARCADIS Avantic

Indications For Use:

The ARCADIS Avantic is a mobile x-ray system which can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Digital Cine Mode (DCM), Subtraction, and Roadmapping, which are necessary to perform a wide variety of clinical procedures. Clinical applications may include, but are not limited to, card/vascular, gastroenterology, electrophysiology, urologic, orthopedic, neurologic, pediatrics, endoscopy, pain therapy and emergency room procedures

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051133